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SECTION 5 – LABORATORY INFORMATION
(COMPLETED BY EACH PRINCIPAL INVESTIGATOR AND APPROVED BY THE RO)

Provide the following information for each principal investigator (PI) working with select agents and toxins at your entity. Make additional copies of this section of the form as needed. Each principal investigator should complete Section 5 as appropriate for *each* laboratory room where select agents and toxins are used or stored. For information on completing this section, refer to page 3 of the guidance document.

SECTION 5A – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR

1. Name of individual responsible for the laboratory (e.g., principal investigator): _____
2. Provide the following information for each select agent(s) and toxin(s) worked with or stored in the laboratory building(s) and room(s):

SELECT AGENT/TOXIN NAME	STRAIN DESIGNATION	DATE ACQUIRED (list N/A if not acquired)	ADDRESS OF FACILITY FROM WHICH THE SELECT AGENT/TOXIN WAS ACQUIRED (Include registration number if applicable)	FACILITY AGENT I.D. (Include any identification used to identify agent unique to laboratory)	SOURCE OF ISOLATE			UNIQUE CHARACTERISTICS	REFERENCE FOR PUBLISHED SEQUENCE INFORMATION (GenBank accession number, journal articles, etc.)
					Clinical	Environmental	Other (explain)		
					☐	☐			
					☐	☐			
					☐	☐			
					☐	☐			
					☐	☐			
					☐	☐			
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SECTION 5B – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (OBJECTIVES OF WORK)

Make additional copies of this section of the form as needed for *each* laboratory room for each principal investigator at your entity. Each principal investigator should complete questions 1 through 101, as appropriate for *each* laboratory where select agents are used or stored. If all laboratories with the same biosafety level under the control of one principal investigator meet the same criteria, then list all laboratory rooms and submit only one form. Include a floor plan for each laboratory where select agents or toxins are to be used or stored.

1. Provide the objectives of the work for each select agent or toxin listed on Table 4A, including a description of the methodologies or laboratory procedures that will be used. State if any host-vector systems will be used. Specify whether work will involve live select agents and recombinant DNA. If no work is being performed on select agent or toxin, indicate storage only. Attach additional sheets if needed:

2. Provide an estimate of the maximum quantities (e.g., number of petri dishes or total volume of liquid media) and concentration of each organism grown at a given time (e.g., 2 - 250 ml flasks of 10^5 cfu/ml). If select agent will not be propagated, then indicate "no propagation of agent". Attach additional sheets if needed:

3. Additional Principal investigators performing the same objective of work: ☐ Yes ☐ No

   If yes, list: _____

SECTION 5C – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (FACILITY)

Include a floor plan for each laboratory where select agents or toxins are to be used or stored (for all laboratory safety levels).

4. Laboratory is currently operational: ☐ Yes ☐ No

   If no, date of anticipated completion of laboratory: _____

5. Floor plan(s) for all laboratory safety levels include:

   a. Entry into laboratory: ☐ Yes ☐ No
   b. Sink locations: ☐ Yes ☐ No
   c. Eyewash locations: ☐ Yes ☐ No
   d. Biological safety cabinet (BSC) locations: ☐ Yes ☐ No
   e. Fume hood locations: ☐ Yes ☐ No
   f. HVAC supply and exhaust locations: ☐ Yes ☐ No
   g. Freezer/refrigerator locations: ☐ Yes ☐ No
   h. Other large equipment locations (incubators, centrifuges, etc): ☐ Yes ☐ No
   i. Autoclave location (if applicable): ☐ Yes ☐ No ☐ N/A
   j. Incinerator location (if applicable): ☐ Yes ☐ No ☐ N/A
   k. Cage washing area (if applicable): ☐ Yes ☐ No ☐ N/A

   NOTE: For BSL-4 or ABSL-4 facility questions, complete Section 5P and all other applicable sections.

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SECTION 5D – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING IN BSL2 LABORATORY(IES)

6. Will work be performed in BSL2 laboratory(ies)? ☐ Yes ☐ No
   If yes, complete questions 7 – 8.

7. Provide a description of the HVAC system (*check all that are appropriate*):
   - ☐ Single-pass ☐ Re-circulated
   - ☐ Dedicated exhaust ☐ Shared exhaust
   - ☐ Constant air volume ☐ Variable air volume
   - ☐ Redundant exhaust fans
   - ☐ Emergency power back-up

8. Provide information on the biological safety cabinets (BSC) in use (For more than one cabinet, provide class and how BSC is connected to HVAC system. Attach additional sheets if needed):
   a. Class of cabinet #1: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
      Class of cabinet #2: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III ☐ N/A
   b. BSC #1 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
      BSC #2 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating ☐ N/A
   c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____

SECTION 5E – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING IN BSL3 LABORATORY(IES)

9. Will work be performed in BSL3 laboratory(ies)? ☐ Yes ☐ No
   If yes, complete questions 10 – 20.

10. Provide a description of the HVAC system (*check all that are appropriate*):
    - ☐ Single-pass ☐ Re-circulated
    - ☐ Dedicated exhaust ☐ Shared exhaust
    - ☐ Constant air volume ☐ Variable air volume
    - ☐ Redundant exhaust fans
    - ☐ Emergency power back-up

11. Provide information on the biological safety cabinets (BSC) in use (For more than one cabinet, provide class and how BSC is connected to HVAC system. Attach additional sheets if needed):
    a. Class of cabinet #1: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
       Class of cabinet #2: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III ☐ N/A
    b. BSC #1 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
       BSC #2 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating ☐ N/A
    c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____

12. Entry into the lab is through a double set of lockable self-closing doors: ☐ Yes ☐ No

13. Each laboratory room has a hands-free sink: ☐ Yes ☐ No

14. An eyewash station is readily available inside the laboratory: ☐ Yes ☐ No

15. All cultures, stock and other regulated wastes are decontaminated before removal from the containment area: ☐ Yes ☐ No
    If yes, describe method:
    - ☐ Autoclaved (temperature, time, and psi): _____
    - ☐ Chemical (disinfectant, concentration, and time): _____
    - ☐ Irradiation: _____
    - ☐ Other: _____

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16. Laboratory exhaust is re-circulated to other areas of the facility: ☐ Yes ☐ No
17. The laboratory is maintained at negative air pressure to provide directional air into the laboratory: ☐ Yes ☐ No
18. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the laboratory: ☐ Yes ☐ No
19. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☐ Yes ☐ No
20. HEPA filtration of all exhaust air is in place: ☐ Yes ☐ No

SECTION 5F – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING IN ABSL2 LABORATORY(IES)

21. Will work be performed in ABSL2 laboratory(ies)? ☐ Yes ☐ No
    If yes, complete questions 22 – 31.
22. Provide a description of the HVAC system (*check all that are appropriate*):
    - ☐ Single-pass ☐ Re-circulated
    - ☐ Dedicated exhaust ☐ Shared exhaust
    - ☐ Constant air volume ☐ Variable air volume
    - ☐ Redundant exhaust fans
    - ☐ Emergency power back-up
23. Provide information on the biological safety cabinets (BSC) in use (For more than one cabinet, provide class and how BSC is connected to HVAC system. Attach additional sheets if needed):
    a. Class of cabinet #1: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
       Class of cabinet #2: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III ☐ N/A
    b. BSC #1 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
       BSC #2 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating ☐ N/A
    c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____
24. Animal laboratories are separated from open and unrestricted areas: ☐ Yes ☐ No
25. Animal laboratory exhaust is re-circulated to other areas of the facility: ☐ Yes ☐ No
26. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: ☐ Yes ☐ No
27. External doors are self-closing, self-locking, and open inward: ☐ Yes ☐ No
28. There is an autoclave in the laboratory: ☐ Yes ☐ No
29. The location of cage washing area is included on floor plan: ☐ Yes ☐ No
    If yes, cage washing is: ☐ Manual ☐ With a mechanical cage washer
30. Each animal room where infected animals are kept contains a hand-washing sink: ☐ Yes ☐ No
31. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

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SECTION 5G – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING IN ABSL3 LABORATORY(IES)

32. Will work be performed in ABSL3 laboratory(ies)? ☐ Yes ☐ No
    If yes, complete questions 33 – 46.

33. Provide a description of the HVAC system (*check all that are appropriate*):
    - ☐ Single-pass ☐ Re-circulated
    - ☐ Dedicated exhaust ☐ Shared exhaust
    - ☐ Constant air volume ☐ Variable air volume
    - ☐ Redundant exhaust fans
    - ☐ Emergency power back-up

34. Provide information on the biological safety cabinets (BSC) in use (For more than one cabinet, provide class and how BSC is connected to HVAC system. Attach additional sheets if needed):
    a. Class of cabinet #1: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
       Class of cabinet #2: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III ☐ N/A
    b. BSC #1 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
       BSC #2 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating ☐ N/A
    c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____

35. Animal laboratories are separated from open and unrestricted areas: ☐ Yes ☐ No
36. Entry into the animal lab is through a double set of lockable self-closing doors: ☐ Yes ☐ No
37. External doors are self-closing, self-locking, and open inward: ☐ Yes ☐ No
38. Each animal room contains a hands-free hand washing sink: ☐ Yes ☐ No
39. Animal laboratory exhaust is re-circulated to other areas of the entity: ☐ Yes ☐ No
40. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: ☐ Yes ☐ No
41. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the animal laboratory: ☐ Yes ☐ No
42. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☐ Yes ☐ No
43. HEPA filtration of all exhaust air is present: ☐ Yes ☐ No
44. There is an autoclave in the laboratory: ☐ Yes ☐ No
45. The location of cage washing area is included on floor plan: ☐ Yes ☐ No
    If yes, cage washing is: ☐ Manual ☐ With a mechanical cage washer
46. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

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SECTION 5H – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (SECURITY)

47. Each laboratory has a site-specific written security plan: ☐ Yes ☐ No

    a. Plan designed according to a site-specific risk assessment and provides graded protection in accordance with the risk of select agent or toxin: ☐ Yes ☐ No

    b. Plan contains all information as required by the Select Agent Regulations: ☐ Yes ☐ No

    c. The plan is reviewed annually and revised as necessary: ☐ Yes ☐ No

    d. Drills or exercises are conducted to validate or test the effectiveness of the plan: ☐ Yes ☐ No

48. Physical Security (check all apply):

    a. Means to limit access to buildings with select agents and toxins:
    - ☐ Guard station at the building entrance
    - ☐ Locks
    - ☐ Card access system
    - ☐ Biometric system
    - ☐ Intrusion detection system
    - ☐ Other (describe): _____

    b. Means to limit access to rooms with select agents and toxins:
    - ☐ Locks
    - ☐ Card access system
    - ☐ Biometric system
    - ☐ Intrusion detection system
    - ☐ Other (describe): _____

    c. Means to limit access to select agents and toxins inside the room:
    - ☐ Locked incubators, refrigerators, freezers, etc.
    - ☐ Locked box inside incubators, refrigerators, freezers, etc.
    - ☐ Biometric system
    - ☐ Card access system
    - ☐ Intrusion detection system
    - ☐ Other (describe): _____

    d. Means to monitor access to areas where select agents and toxins are used or stored:
    - ☐ Electronic logs of access
    - ☐ Manual sign in logs
    - ☐ Video camera surveillance
    - ☐ Other (describe): _____

    e. Access to select agents and toxins is restricted to individuals that have access approval from the APHIS Administrator or HHS Secretary: ☐ Yes ☐ No

    f. Are individuals not approved for access from the APHIS Administrator or HHS Secretary allowed access to an area with select agents and toxins? ☐ Yes ☐ No

    1) If yes, are these individuals allowed into the area escorted? ☐ Yes ☐ No

    2) If no, explain: _____

    g. The laboratory is secured when no one is present during regular working hours: ☐ Yes ☐ No

49. Suspicious packages are inspected prior to entry or removal from an area where select agents and toxins are used or stored: ☐ Yes ☐ No

50. Select agents and toxins are transferred within the entity (intra-entity transfers): ☐ Yes ☐ No

    a. Intra-entity transfer is only under the supervision of an individual with access approval from APHIS Administrator or HHS Secretary: ☐ Yes ☐ No

    b. Chain-of-custody documents are used for intra-entity transfers: ☐ Yes ☐ No

51. Select agents and toxins are transferred from a laboratory to a shipping area and vice versa only under the supervision of an individual with access approval from APHIS Administrator or HHS Secretary: ☐ Yes ☐ No

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SECTION 5I – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (BIOSAFETY AND INCIDENT RESPONSE)

52. Each laboratory has a written agent-specific, site-specific biosafety plan: ☐ Yes ☐ No
    a. The plan is commensurate with the risk of the select agent and toxin and contains all information as required by the Select Agent Regulations: ☐ Yes ☐ No
    b. The plan is reviewed annually and revised as necessary: ☐ Yes ☐ No
    c. Drills or exercises are conducted to validate or test the effectiveness of the plan: ☐ Yes ☐ No
53. Appropriate personal protective equipment (PPE) is used: ☐ Yes ☐ No ☐ N/A
54. A medical surveillance system is in place for personnel using the select agents and toxins: ☐ Yes ☐ No ☐ N/A
55. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported: ☐ Yes ☐ No
56. A sharps policy is in place for this laboratory: ☐ Yes ☐ No
57. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with select agents and toxins at this facility? ☐ Yes ☐ No
    If yes, has the IBC approved the work proposed in this application: ☐ Yes ☐ No
58. The facility has been inspected by USDA, FDA, CLIA, DoE, DoD or others: ☐ Yes ☐ No
    If yes, then give agency name and date of last inspection(s): _____
59. Each laboratory has a written incident response plan: ☐ Yes ☐ No
    a. The plan is commensurate with the hazards of the select agent and toxin and contains all information as required by the Select Agent Regulations: ☐ Yes ☐ No
    b. The plan is reviewed annually and revised as necessary: ☐ Yes ☐ No
    c. Drills or exercises are conducted to validate or test the effectiveness of the plan: ☐ Yes ☐ No

SECTION 5J – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (TRAINING)

60. Training:
    a. Security and biosafety training is provided prior to individual's access to areas where select agents and toxins are handled or stored: ☐ Yes ☐ No
    b. Training addresses the needs of the individual, the work being performed, and risks posed by select agents and toxins: ☐ Yes ☐ No
    c. Refresher training is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency): _____
    d. Written records of individuals trained are kept: ☐ Yes ☐ No
    e. Personnel demonstrate proficiency in laboratory procedures prior to working with select agents and toxins: ☐ Yes ☐ No
    f. Provide a brief description of what is included in the training program:
        ☐ Biosafety: _____
        ☐ Incident Response: _____
        ☐ Security: _____
        ☐ Other: _____
    g. Describe the means used to verify that individuals understood the training (add additional sheets as necessary):
        _____

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SECTION 5K – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (RECORDS AND INFORMATION SYSTEMS CONTROL)

61. Complete records are maintained as required by the Select Agent Regulations: ☐ Yes ☐ No

62. Provide a brief explanation of the system in place that ensures records and databases are accurate, their authenticity may be verified, and explains any discrepancies:

_____

63. Describe the means to control access to records and databases that would allow for access to select agents and toxins:
- ☐ Locks
- ☐ Locked filing cabinet, drawer, cabinet, etc.
- ☐ Secured electronic database (e.g., password protected, "stand alone PC")
- ☐ Card access system
- ☐ Other: _____

a. Are these records and databases located on any computer on a network? ☐ Yes ☐ No

If yes, provide a brief explanation of the systems in place to prevent unauthorized access to select agents and toxins (e.g., password protected, firewall protection)? _____

_____

64. Name(s) of Individual(s) responsible for inventory of select agent(s) and toxin(s): _____

a. Inventory record is reconciled: ☐ Annually ☐ Biannually ☐ Other (specify frequency): _____

b. Inventory tracking includes the following information (list): _____

_____

_____

SECTION 5L – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH TOXINS

65. Will work be performed with toxins or with agents that produce regulated amounts of toxins? ☐ Yes ☐ No
If yes, complete questions 66 – 71.

66. A Chemical Hygiene Plan is available for the laboratory using toxins: ☐ Yes ☐ No

67. Maximum quantity of each toxin under the control of the principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, at a given time:

a. Toxin: _____ Aggregate amount of Toxin: _____

b. Toxin: _____ Aggregate amount of Toxin: _____

c. Toxin: _____ Aggregate amount of Toxin: _____

68. Form of toxins used: ☐ Liquid ☐ Lyophilized ☐ Not Applicable-Storage Only

69. The toxin is produced by viable agent at the entity: ☐ Yes ☐ No

a. If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____

70. Dilution procedures and other manipulations of the concentrated toxins are performed: ☐ Yes ☐ No

a. If yes, conducted in: ☐ Fume hood ☐ Biological safety cabinet

b. If a fume hood or biosafety cabinet is used, certification is conducted:
☐ Annually ☐ Biannually ☐ Other (describe): _____

c. Work is conducted with two knowledgeable people present: ☐ Yes ☐ No

71. A hazard sign is posted on the door when toxins are in use: ☐ Yes ☐ No

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SECTION 5M – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH GENETIC ELEMENTS, RECOMBINANT NUCLEIC ACIDS, OR RECOMBINANT ORGANISMS

72. Will work be performed with genetic elements, recombinant nucleic acids, or recombinant organisms? ☐ Yes ☐ No / ☐ Yes ☐ No / ☐ Yes ☐ No

If yes, complete questions 73 – 77.

73. The biosafety level listed in Section 4A for this laboratory meets NIH guidelines: ☐ Yes ☐ No

74. Will you be possessing, using or transferring the following:

a. Nucleic acids that can produce infectious forms of any of the select agent viruses. ☐ Yes ☐ No

b. Recombinant nucleic acids that encode for the functional form(s) of any select toxins if the nucleic acids:

1) can be expressed in vivo or in vitro. ☐ Yes ☐ No

2) are in a vector or recombinant host genome and can be expressed in vivo or in vitro. ☐ Yes ☐ No

c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☐ No

75. Provide a brief description of the recombinant constructs and any associated expression control elements, including what the recombinant DNA encodes for, if known: _____

76. Give an estimate of range of length of recombinant DNA to be used: _____

77. Are you intending to conduct the following restricted experiments as defined under 7 CFR 331.13, 9 CFR 121.13, and 42 CFR 73.13? ☐ Yes ☐ No

a. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture: ☐ Yes ☐ No

If yes, provide a brief description of the restricted experiment: _____

_____

b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD_{50} < 100 ng/kg body weight: ☐ Yes ☐ No

If yes, provide a brief description of the restricted experiment: _____

_____

Note: An individual or entity may not conduct a restricted experiment with select agents and toxins unless approved by the APHIS Administrator and HHS Secretary.

SECTION 5N – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH ANIMALS

78. Will work be performed with animals? ☐ Yes ☐ No
If yes, complete questions 79 – 84.

79. List species of animals that will be used: _____

80. Describe route of administration of select agent or toxin: _____

81. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.) by an approved method:
☐ Not treated
☐ Autoclaved (temperature, time, and psi): _____
☐ Chemical (disinfectant, concentration, and time): _____
☐ Irradiation: _____
☐ Other: _____

82. Carcasses of animals are disposed of on site: ☐ Yes ☐ No

a. If yes, provide method of disposal of treated carcasses:

☐ Incineration ☐ Rendering ☐ Chemical decomposition ☐ Other (*describe*): _____

b. If no, describe: _____

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83. The entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this entity: ☐ Yes ☐ No

    If yes, the proposed work with select agents and toxins in animals has been approved by the IACUC: ☐ Yes ☐ No

84. The laboratory is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC): ☐ Yes ☐ No

    If yes, give accreditation date: _____

SECTION 5O – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH PLANTS

85. Will work be performed with plants? ☐ Yes ☐ No
    If yes, complete questions 86 – 93.

86. Work will be done in a glass or greenhouse: ☐ Yes ☐ No

    If yes, provide a description of the glass or greenhouse:

    ☐ Laminated Glass ☐ Tempered Glass ☐ Lexan ☐ Other (*describe*): _____

87. Structure is reinforced: ☐ Yes ☐ No

88. Floor is concrete: ☐ Yes ☐ No

89. Vents in facility: ☐ Yes ☐ No

90. Waste water collection and treatment: ☐ Yes ☐ No

91. Greenhouse HVAC supply and exhaust:

    a. Negative air pressure is maintained inside greenhouse: ☐ Yes ☐ No

    b. Greenhouse exhaust is re-circulated to other areas of the facility: ☐ Yes ☐ No

        If yes, HEPA filtration of all exhaust air is in place: ☐ Yes ☐ No

    c. Provide a description of the HVAC system (*check all that are appropriate*):

    ☐ Single-pass ☐ Re-circulated
    ☐ Dedicated exhaust ☐ Shared exhaust
    ☐ Constant air volume ☐ Variable air volume
    ☐ Redundant exhaust fans
    ☐ Emergency power back-up

92. Vectors present: ☐ Yes ☐ No
    If yes, vectors are restricted to cages: ☐ Yes ☐ No

93. Plant waste is treated prior to disposal (e.g., soil, plant material, etc.) by an approved method:

    ☐ Not treated
    ☐ Autoclaved (temperature, time, and psi): _____
    ☐ Chemical (disinfectant, concentration, and time): _____
    ☐ Irradiation: _____
    ☐ Other: _____

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SECTION 5P – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING IN BSL4/ABSL4 LABORATORIES

94. Will work be performed in BSL4/ABSL4 Laboratory? ☐ Yes ☐ No
    a. If yes, complete questions 95 – 101.

    b. Activities conducted under BSL-4/ABSL4 laboratory (check all that apply):
    ☐ Research ☐ Small animal
    ☐ Diagnostic ☐ Large animal
    ☐ Large scale production ☐ Recombinant DNA
    ☐ Other (give description): _____

95. What type of BSL-4 laboratories are you registering?
    ☐ Stand alone Class III cabinet laboratory (complete question 99)
    ☐ Protective suit laboratory (complete question 100)
    ☐ Protective suit laboratory with associated Class III cabinet (complete questions 99 and 100)
    ☐ ABSL-4 Stand alone Class III cabinet laboratory (complete questions 99 and 101)
    ☐ ABSL-4 Protective suit laboratory (complete questions 100 and 101)
    ☐ ABSL-4 Protective suit laboratory with associated Class III cabinet (complete all questions)

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96. Provide a description of the HVAC system (*check all that are appropriate*):
    ☐ Single-pass ☐ Re-circulated
    ☐ Dedicated exhaust ☐ Shared exhaust
    ☐ Constant air volume ☐ Variable air volume
    ☐ Redundant exhaust fans
    ☐ Emergency power back-up

97. Provide information on the biological safety cabinets (BSC) in use (For more than one cabinet, provide class and how BSC is connected to HVAC system. Attach additional sheets if needed):
    a. Class of cabinet #1: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
    Class of cabinet #2: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III ☐ N/A
    b. BSC #1 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
    BSC #2 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating ☐ N/A
    c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____

98. Provide safety information for the BSL-4 laboratory facility(ies) you are registering by answering the questions in this section. Use separate sheets if necessary.
    a. A specific BSL-4 facility operations manual has been prepared: ☐ Yes ☐ No
    b. All standard BSL-4 microbiological practices are followed: ☐ Yes ☐ No
    c. There is a mandatory daily inspection of the containment parameters for the BSL-4 laboratory area(s) and critical life support systems: ☐ Yes ☐ No
    d. Walls, floors, and ceilings of the BSL-4 laboratory rooms are sealed. All penetrations into the laboratory are sealed: ☐ Yes ☐ No
    e. A visual pressure differential monitoring system is provided at the clean change room for laboratory personnel to verify directional air before entry into the BSL-4 laboratory: ☐ Yes ☐ No
    f. Differential pressures/directional airflow between adjacent areas is monitored and alarmed (visually and audibly) to indicate system failure: ☐ Yes ☐ No
    g. Double HEPA filtration of all suit area, decontamination shower, decontamination airlock and Class III cabinet exhaust air is in place: ☐ Yes ☐ No
    h. Single HEPA filtration of all suit area, decontamination shower, decontamination airlock and Class III cabinet supply air is in place: ☐ Yes ☐ No

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Principal investigator: _____ Date: _____
Laboratory building: _____ Laboratory room number(s): _____ Laboratory Safety Level: _____

i. Describe method utilized for decontamination of BSL-4 area(s):

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99. Entities registering a stand alone Class III cabinet laboratory must complete the following information:

a. Inner and outer change rooms are separated by a shower for personnel entering and leaving the cabinet room: Yes No

b. There is a double-door (pass-through) autoclave, dunk tank, fumigation chamber, or ventilated anteroom for passing materials, supplies, or equipment into or out of the cabinet room: Yes No

c. Walls, floors, and ceilings of the cabinet room(s) are sealed and all penetrations into the cabinet room(s) are sealed: Yes No

d. Floors are seamless and coved: Yes No

e. All drains in the cabinet room(s), inner change room(s), and autoclave chambers connect directly to an appropriate liquid waste decontamination system: Yes No

f. Sewer vents and other service lines contain HEPA filters: Yes No

g. Bench tops are seamless or sealed surfaces that are impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and other decontaminant chemicals: Yes No

h. Laboratory furniture is capable of supporting anticipated loads and uses and is covered with a non-fabric material that can be easily decontaminated: Yes No

i. If a central vacuum system is present, it serves only the cabinet room(s) and is HEPA filter protected, and liquid and gas services to the cabinet room are protected by backflow prevention devices: Yes No

j. Any windows are break resistant and sealed: Yes No

k. Double-door autoclaves are provided for decontamination of materials removed from the Class III cabinet and the cabinet room. These autoclaves are interlocked so that the outside door can only be opened after the sterilization cycle is complete: Yes No

l. Pass-through dunk tanks, fumigation chambers, or equivalent decontamination methods are provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from both the Class III biological safety cabinet(s) and the cabinet room(s): Yes No

m. All HEPA filters are tested and certified annually: Yes No

n. An HVAC monitoring system is provided to avoid pressurization of the laboratory and is alarmed to warn laboratorians of exhaust system failure: Yes No

o. There is HEPA filtration of all supply and exhaust air from the cabinet room(s), inner change room(s), and anteroom(s): Yes No

p. The Class III cabinet is directly connected to the exhaust system with HEPA filtration on the supply and double HEPA filtration on the exhaust: Yes No

q. Appropriate communication systems are provided between the laboratory and external personnel (intercom, phone, fax, and computer): Yes No

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100. Entities registering a protective suit laboratory must complete the following information:

a. Entry into the area(s) where work is performed with BSL-4 select agents [suit room(s)] is through a series of changing and decontamination areas separated by airtight doors: Yes No

b. Inner and outer change rooms are separated by a personal shower: Yes No

c. A chemical shower is provided for decontaminating the outer surface of the protective suit: Yes No

d. A breathing air system is provided with redundant compressors, backup storage tanks, HEPA filtration protection, and alarm monitoring in the event of failure: Yes No

e. All penetrations into containment shell (walls, floors, and ceilings) of the suit area(s), chemical shower(s), and airlock(s) are sealed: Yes No

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Principal investigator: _____ Date:
Laboratory building: _____ Laboratory room number(s): _____ Laboratory Safety Level: _____

f. Daily inspections of the containment parameters and life support systems are performed, completed and documented before laboratory work begins: Yes No

g. A double-door, interlocked autoclave is provided for decontaminating waste materials removed from the suit area(s): Yes No

h. A dunk tank, fumigation chamber, or ventilated airlock to pass materials, supplies, or equipment into or out of the suit area(s): Yes No

i. Bench tops are seamless surfaces that are impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and other decontaminant chemicals: Yes No

j. Laboratory furniture is capable of supporting anticipated loads and uses and is covered with a non-fabric material that can be easily decontaminated: Yes No

k. If a central vacuum system is present, it serves only the suit area(s) and is protected by HEPA filtration: Yes No

l. Liquid and gas services to the suit area(s) are protected by backflow devices: Yes No

m. Inner and outer doors to chemical showers and airlocks are interlocked to prevent both doors from being opened at the same time: Yes No

n. Any windows are break resistant and sealed: Yes No

o. All drains in the suit area(s), chemical shower(s), and autoclave chambers connect directly to an appropriate liquid waste decontamination system: Yes No

p. An HVAC monitoring system is provided to avoid pressurization of the laboratory and is alarmed to warn laboratorians in the event of exhaust system failure: Yes No

q. Redundant exhaust fans are installed: Yes No

r. All HEPA filters are tested and certified annually: Yes No

s. HVAC supply to the suit area(s), chemical shower(s), and airlock(s) is HEPA filtered: Yes No

t. HVAC exhaust from the suit area(s), chemical shower(s), and airlock(s) is double HEPA filtered with the HEPA filters in series: Yes No

u. Appropriate communication systems are provided between the laboratory and external personnel (intercom, phone, fax, and computer): Yes No

v. Emergency lighting and emergency communications systems are provided for the BSL-4 areas: Yes No

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101. Entities registering an ABSL-4 laboratory must complete the following information:

a. Specific procedures have been developed for handling animals under ABSL-4 conditions in the Class III cabinet or protective suit laboratories being registered: Yes No

b. Aerosol experiments are conducted in this ABSL-4 laboratory: Yes No

c. Describe how animals are housed under ABSL-4 conditions (add additional sheets as necessary):

d. Personnel assigned to work with infected animals work in pairs: Yes No

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APHIS/CDC FORM 1 (12/31/2008)
(CDC Adobe Acrobat 5.0 Electronic Version, 1/2006)

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